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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JESSICA PENELOW and CHRISTINE BRANCACCIO,	:	Case No. 12-7758 (ZNQ)(JBD)
Plaintiffs,	:	
v.	:	
JANSSEN PRODUCTS, LP,	:	
Defendant.	:	

RELATORS' TRIAL BRIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Pursuant to the Court's Final Pretrial Order dated November 2, 2022 (Dkt. 315, p. 91, ¶15 A.), Relators Christine Brancaccio and Jessica Penelow submit this Trial Brief to address issues of law and other relevant trial considerations.[1]

The crux of this False Claims Act case is that Defendant Janssen Products, LP ("Janssen"), a pharmaceutical company and subsidiary of Johnson & Johnson, knowingly engaged in a nationwide kickback scheme and off-label marketing scheme to unlawfully increase the sales of two of its HIV/AIDS drugs, Prezista and Intelence, thereby causing hundreds of millions of dollars in damages to government health care programs.

This Trial Brief addresses pertinent legal issues surrounding Relators' claims, Janssen's defenses, and the trial of this action.

I. LEGAL ISSUES REGARDING RELATORS' KICKBACK CLAIMS

With regard to Relators' kickback claims, Relators will prove that Janssen used its Speaker Program as a means to pay kickbacks to hundreds of physician-speakers to induce them to prescribe Prezista and Intelence or to reward them for doing so, in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320(a)-7b(b)(2)(B), the False Claims Act ("FCA"), 31 U.S.C. § 3129 *et seq*., and the Plaintiff States' false claims acts.

[1] This Trial Brief focuses on apparent disputed issues of law, and Relators are not attempting to address all legal issues in this case. If Janssen raises additional disputed issues in its Trial Brief, Relators will then respond in their opposition brief.

A. Relators Only Need to Show that at Least One Purpose of Janssen's Payments to Physician-Speakers Was to Induce or Reward Prescriptions

Relators allege that, from 2006 to 2014, Janssen paid illegal kickbacks to hundreds of physician-speakers, primarily under the guise of its Speaker Program, in order to induce them to prescribe Prezista and Intelence and/or to reward them for doing so, in violation of the AKS and FCA.

In order to prove their kickback claims, Relators need not prove that inducing or rewarding prescriptions was the sole or primary reason for Janssen's payments to physician-speakers. Rather, Janssen's payments to prescribers violate the AKS so long as at least "one purpose" of the payments was to induce or reward them to prescribe. *See United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985).[2] In other words, the "one purpose" test focuses on Janssen's reasons for providing remuneration to prescribers. Notably, this Court has accepted the "one purpose rule" when denying Janssen's Motion for Summary Judgment, (Dkt. 291, p. 23), and Janssen acknowledges the rule in the Final Pretrial Order (Dkt. 315, p. 86).

[2] *See also Purcell v. Gilead Scis., Inc.*, 439 F. Supp. 3d 388, 398 (E.D. Pa. 2020) ("It is sufficient if at least 'one purpose of the payment was to induce' Medicare purchases."); *see also United States ex rel. Judd v. Quest Diagnostics Inc.*, CIV. 10-4914 KM, 2014 WL 2435659, at *12 n.11 (D.N.J. May 30, 2014), *aff'd*, 638 Fed. Appx. 162 (3d Cir. 2015) (same); *see also United States ex rel. Gohil v. Sanofi U.S. Services, Inc.,* CV 02-2964, 2020 WL 4260797, at *9 (E.D. Pa. July 24, 2020) ("Relator does not have to prove that this is the 'sole purpose' of the remuneration, and it is irrelevant if the remuneration has another, more benign purpose").

B. Relators Will Establish Liability and Causation By Showing that Janssen made Payments to Doctors and the Doctors Prescribed Janssen's Drugs

To establish Janssen's AKS liability and causation, Relators only need to show that: (1) Janssen knowingly and willfully offered or paid remuneration to prescribers, one purpose of which was to induce them to prescribe Prezista or Intelence, (2) the prescribers thereafter prescribed those drugs, and (3) claims for payment for those prescriptions were submitted to a government health care program. *See United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96–100 (3d Cir. 2018) (holding the Government need only show a "link"—not but for causation—between the individual or entity receiving a kickback and the submission of a claim for reimbursement to a federal health care program).[3]

Janssen will likely argue that Relators must prove that the remuneration that Janssen provided to physicians directly caused those physicians to write prescriptions for Prezista and Intelence that they otherwise would not have written,

[3] *United States ex rel. Bawduniak v. Biogen Indec, Inc.*, 12-CV-10601-IT, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) ("It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, *even if* the physician would have prescribed those drugs absent the kickback"); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011), *overruled on other grounds as recognized by United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburg*, 728 F. App'x 101 (3d Cir. 2018) (holding the FCA requires "a participant in a federal health care program to refrain from offering or entering into payment arrangements which violate the AKS, while making claims for payment to the Government under that program").

that the physicians had a *quid pro quo* arrangement with Janssen to prescribe these drugs, and/or that the physicians themselves broke the law. Such arguments are contrary to established law.

It is well-settled that, to prove liability under the AKS, the plaintiff is not required to show that a kickback actually affected the doctor's prescribing decisions, or that there was any *quid pro quo* arrangement between the kickback provider and recipient. *See Greenfield*, 880 F.3d at 96-100 (rejecting an argument that the FCA requires a plaintiff "to prove a kickback actually influenced a patient's or medical professional's judgment").[4] Instead, Relators must identify a link between the alleged kickbacks and the false claims, which is established by showing that a doctor who received a kickback thereafter wrote prescriptions for the relevant drugs for

[4] *See also Bawduniak*, 2018 WL 1996829, at *3, 6 (liability can be established "regardless of whether the claim was the result of a quid-pro-quo exchange or would have been submitted even absent the kickback"); *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc*., No. 13-CV-3003 (WMW/DTS), 2021 WL 101193, at *12, 14–16 (D. Minn. Jan. 12, 2021) ("[A]n increase in the purchase or utilization of Defendant's products after a kickback was paid is not relevant to causation, nor is but-for causation an element of Plaintiffs' claim."). "Notably, the AKS does not require a kick-back scheme to succeed in generating new business (*i.e.*, new patient prescriptions) in order for a violation to have occurred.'" *United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 263 (S.D.N.Y. 2014); *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc*., 500 F. Supp. 3d 345, 366–367 (E.D. Pa. 2020) (quoting *Greenfield* and holding that relator "does not need to prove a kickback 'actually influenced a patient's or medical professional's judgment'"); *Kuzma v. N. Arizona Healthcare Corp*., 607 F. Supp. 3d 942, 953–957 (D. Ariz. 2022) (following *Greenfield*, *Teva*, and *Bawduniak*); *United States v. Regeneron Pharm., Inc.,* No. CV 20-11217-FDS, 2020 WL 7130004, at *11 (D. Mass. Dec. 4, 2020) (following *Greenfield* and *Bawduniak*).

which a claim was submitted to a government health care program. *See Greenfield*, 880 F.3d at 99–100.

The Third Circuit's decision in *Greenfield* is instructive here. That case involved allegations that Accredo, a specialty pharmacy, paid kickbacks to two charities, "HSI" and "HANJ," to induce the charities to refer their members to Accredo. *Id*. at 91–92. To survive summary judgment, the Third Circuit held that the relator had to "point to at least one claim [submitted to a federal health care program] that covered a patient who was recommended or referred to Accredo by HSI/HANJ." *Id*. at 99. The relator did not, however, have to show that the patient would not have been recommended or referred to Accredo absent the kickbacks or that the kickbacks otherwise caused the recommendation or referral. *Id*., at 99–100. Similarly, here, Relators must show that a doctor who received a kickback thereafter wrote a prescription for Prezista or Intelence for which a claim was submitted to a government health care program, but Relators need not show that the kickbacks actually affected the doctors' prescribing decisions.

The Court's ruling in *United States ex rel. Arnstein v. Teva Pharmaceuticals USA, Inc.*, another *qui tam* action involving alleged kickbacks to doctors through speaker programs, is directly on point. No. 13 CIV. 3702 (CM), 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019). In *Teva*, the defendant drug manufacturer argued on summary judgment that, to prevail, the relators must prove that a *quid pro quo*

arrangement or kickback caused a doctor to write additional prescriptions. *Teva*, 2019 WL 1245656, at *23-27. The Court rejected this argument, explaining that plaintiffs need only show that the defendant provided a kickback to a doctor and that the doctor subsequently wrote one or more prescriptions for that company's drugs:

> Relators need not show that a quid pro quo exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks. It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback.

Id. at *24 (*quoting Bawduniak*, 2018 WL 1996829, at *3). The Court should apply the same standard here.

Finally, Relators need not prove that the physician-speakers knowingly and willfully accepted bribes or otherwise broke the law. While the AKS permits the Government to pursue those—like the doctors here—who "solicit[] or receive[]" kickbacks, 42 U.S.C. § 1320-7b(b)(1), Relators have not sued the individual doctors. Relators have sued Janssen, and thus, the operative AKS provision here is subsection (b)(2), which addresses those—like Janssen here—who "offer[] or pay[]" kickbacks, 42 U.S.C. § 1320-7b(b)(2). Janssen's payment of such kickbacks itself constituted a violation of the AKS under subsection (b)(2), regardless of whether the doctors' acceptance of the kickbacks constituted a separate violation of the AKS under subsection (b)(1). Accordingly, to establish Janssen's liability, Relators need not

prove that any particular doctor violated the AKS or acted with any particular mental state.

As a factual matter, in this case, the evidence, including CMS prescription claims data, clearly demonstrates that the paid physician-speakers continued to prescribe Prezista and Intelence after Janssen paid them. Some of these doctors received hundreds of thousands of dollars from Janssen, and Janssen monitored the prescription activity of its drugs' prescribers. The question for the jury, then, is whether one purpose of the remuneration provided to prescribers was to increase prescriptions for Prezista and Intelence.

C. Remuneration may be Unlawful Even if it Reflects Fair Market Value

For Relators' kickback claims, the illegal remuneration at issue is primarily the money Janssen paid to physician-speakers in fees and expenses (in addition to paid trips, hotel stays, dinners, and similar remuneration) in order to induce them to prescribe Janssen's drugs or to reward them for doing so. Courts have construed the term "remuneration" to mean "anything of value—and in any form—which is given in return for, or to induce, a referral for federal healthcare services." *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 677 (W.D. Pa. 2014); *see also United States v. Health All. of Greater Cincinnati*, No. 1:03-CV-00167, 2008 WL 5282139, at *6–7 (S.D. Ohio Dec. 18, 2008).

Even if the amounts of the speakers' fees reflect fair market value, they may still constitute illegal remuneration under the law.[5] If the remuneration is intended to induce referrals, it is unlawful—even where the remuneration is fair market value. *Ashcroft*, 39 F. Supp. 3d, at 677.[6]

II. LEGAL ISSUES REGARDING RELATORS' OFF-LABEL CLAIMS

Regarding Relators' off-label ("OL") marketing claims, Relators will prove that Janssen engaged in the false, misleading, and OL promotion of Prezista and

[5] It is unclear whether Janssen intends to advance any arguments based on alleged fair market value of the remuneration paid to prescribers. This Court has recognized that the phrase "fair market value" arises in a few safe harbors to the AKS. *United States ex rel. Perri v. Novartis Pharm. Corp*., No. CV 15-6547, 2019 WL 6880006, at *13 (D.N.J. Feb. 21, 2019). Janssen would bear the burden of establishing the applicability of any safe harbor. *Id* at * 14. However, Janssen did not put any safe harbors or affirmative defenses at issue in the Final Pretrial Order entered by the Court on November 2, 2022.

[6] *See Novartis Pharm. Corp*., 2019 WL 6880006, at *13 n.14 (acknowledging "there may be situations where an exchange is an illegal 'remuneration' within the meaning of AKS, even though the exchange itself is for 'fair market value'"); *United States ex rel. Patel v. Cath. Health Initiatives*, 312 F. Supp. 3d 584, 596 (S.D. Tex. 2018) ("The presence of a legitimate business purpose for the arrangement or a fair market value payment will not legitimize a payment if there is also an illegal purpose"); *United States ex rel. Boise v. Cephalon, Inc*., No. CIV.A. 08-827, 2015 WL 1724572, at *10 (E.D. Pa. April 15, 2015) ("[R]elators need not allege that speaker fees were provided at higher than market rates for similar speaking engagements in order to constitute kickbacks underlying a theory of FCA liability."); *United States ex rel. Health Dimensions Rehab., Inc. v. Rehabcare Group, Inc.,* No. 4:12CV00848 AGF, 2013 WL 4666338, at *5 (E.D. Mo. Aug. 30, 2013) ("Lack of fair market value, per se, is not an element the Government must provide").

Intelence, including through sales calls and at Speaker Programs that resulted in false claims, in violation of the FCA.

A. The Off-Label Claims for Prescriptions for Prezista and Intelence Were False

At trial, Relators will prove that Janssen improperly promoted (1) Prezista for treatment-naïve patients prior to its approval for those patients in October 2008; (2) Prezista as "lipid neutral," "lipid friendly," or comparable to Reyataz in terms of its impact on lipids, contrary to its FDA-approved label; (3) Intelence for treatment-naïve patients when it was never approved for those patients; and (4) Intelence for once-daily dosing when it was only FDA-approved for twice-daily dosing. Relators' evidence will establish that these four OL marketing claims are "false" or "fraudulent" under the FCA and analogous State FCAs.

As this Court has previously recognized, "[a] claim is 'legally false' when the claimant misrepresents that he or she has complied with 'statutory, regulatory, or contractual requirement[s].'" *United States ex rel. Penelow v. Janssen Products, LP*, No. CV127758ZNGLHG, 2021 WL 6052425, *7 (D.N.J. Dec. 21, 2021) (Quraishi, J.) (citation omitted). The falsity requirement can be satisfied by alleging implied false certifications or express false certifications. *See ex rel. Wilkins*, 659 F.3d at 305–306. Here, Relators will present evidence proving both theories of falsity: (1) Janssen caused the submission of claims for Prezista and Intelence to the government that impliedly certified eligibility for payment when, in fact, the claims were

statutorily ineligible for payment; and (2) Janssen caused other health care entities to make express false certifications that the claims submitted to the government for Prezista and Intelence complied with the law, when in fact they did not. *See* Dkt. 315, § 11.

B. All of the Off-Label Claims Were False Because They Were Statutorily Ineligible for Reimbursement

It is not disputed that, under the FCA, a claim is "false" if it is statutorily ineligible for reimbursement.[7] As discussed more fully below, certain of Relators' OL claims were statutorily ineligible for reimbursement because they were not prescribed for a medically accepted indication, as required under the law governing government health care program reimbursement. Further, Relators' Prezista Lipids claims were statutorily ineligible for reimbursement as they were not reasonable and necessary for the treatment of patients with lipid issues.

[7] This is based on the implied certification theory of falsity that "anyone who submits a claim to the government impliedly certifies compliance with all the conditions of payment." *United States ex rel. Brown v. Celgene*, 226 F. Supp. 3d 1032, 1044 (C.D. Cal. 2016) (citation omitted).

C. Relators' OL Claims of Prezista Treatment Naïve, Intelence Treatment Naïve, and Intelence Once-Daily Were Statutorily Ineligible for Reimbursement as They Were Not Prescribed for "Medically Accepted Indications"

Government health care programs will only cover and pay for a drug that is used for a "medically accepted indication," which means any FDA-approved use that is supported by one or more citations in certain drug compendia.[8]

As Relators will prove at trial, Intelence and Prezista prescriptions written for treatment-naïve patients and Intelence prescriptions to be dosed once-daily were not FDA-approved uses or indications, not supported by the relevant compendia, and, thus, not reimbursable by the government. These claims are legally false. It should be noted that Janssen has ***never*** challenged the falsity of these OL Claims (*i.e.,* Prezista Treatment Naïve, Intelence Treatment Naïve or Intelence Once-Daily).

D. The Prezista Lipid Claims were Statutorily Ineligible for Reimbursement as They Were Not Reasonable and Necessary for Treatment of Patients with Lipid Issues[9]

As already determined by the Court in this case, Medicare only covers and pays for a drug that is "reasonable and necessary for the diagnosis or treatment of illness or injury." *See ex rel. Penelow*, 2021 WL 6052425, at *5 (citing 42 U.S.C. §

[8] *See* 42 U.S.C. § 1395w-102(e)(1); 42 U.S.C. § 1395y(a)(l)(A); 42 U.S.C. §§ 1396r-8(d)(1)(B)(i), (g)(1)(B)(i) and (k)(6).

[9] Relators reserve the right to present evidence and argument that all OL-induced prescriptions were not reasonable and necessary.

1395w-102(e)(3); 42 U.S.C. § 1395y(a)(I)(A)) (Quraishi, J.); *United States ex rel. Penelow v. Johnson & Johnson, et al.*, 2017 WL 2367050, *4 (D.N.J. May 31, 2017) (Shipp, J.); *see also* 42 U.S.C. §§ 1395w-102(e)(1), (e)(3); 42 U.S.C. § 1395y(a)(l)(A); 42 C.F.R. § 411.15(k)(1). Thus, a claim that is not medically reasonable or necessary is ineligible for reimbursement by the government and, therefore, false under the FCA.[10]

The evidence shows that, as a result of Janssen's false and misleading OL marketing, Prezista claims were submitted to the government for prescriptions for patients with lipid problems. These claims were medically unreasonable and unnecessary because Prezista was generally not appropriate for patients with lipid

[10] *See United States ex rel. Bergman v. Abbott Labs.*, 995 F. Supp. 2d 357, 367 (E.D. Pa. 2014)(prescriptions for uses that are "'not reasonable and necessary for treatment,' makes those uses ineligible for reimbursement under Medicare and Medicaid regulations."); *United States ex rel. Strom v. Scios, Inc.*, 676 F. Supp. 2d 884, 891 (N.D. Cal. 2009) (Because CMS "permits reimbursement only for 'reasonable and necessary' treatments, a prescription of [a drug] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement."); *see also United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730, 742 (10th Cir. 2018) (in an FCA case involving eligibility for payment under Medicare, "a claim is false if it is not reimbursable, and a Medicare claim is not reimbursable if the services provided were not medically necessary"); *see also Diamond v. Sec'y of Health & Hum. Servs.*, No. 1:13 CV 2481, 2015 WL 367010, at *6 (N.D. Ohio Jan. 27, 2015) (holding in a Medicare Part D coverage case that the "relevant statutes create two coverage requirements under Part D"—that the medication be "'reasonable and necessary'" for the patient and "prescribed for a 'medically accepted indication'")

problems as its FDA-approved label included Serious Adverse Drug Reactions regarding lipids. Further, there was an alternative drug from a different manufacturer that did not pose lipid concerns.

Janssen has twice tried to dismiss Relators' Prezista lipid claims and twice has been denied. *See ex rel. Penelow*, 2017 WL 2367050, at *4-6 (denying dismissal of lipid claim on motion to dismiss); *see also ex rel. Penelow*, 2021 WL 6052425, at *12 (D.N.J. Dec. 21, 2021) (denying summary judgment on Prezista lipid claim).

E. Relators Will Also Prove That All of the Off-Label Claims Were False Based on the Express False Certification Theory

Relators also intend to prove falsity of all of the OL claims through an express false certification theory. Relators' evidence supports an express false certification theory by showing that Janssen caused pharmacies to make false certifications that claims submitted to the government for Prezista for patients with lipid issues complied with the law, when in fact they did not because they were not for medically accepted indications and/or for a reasonable or necessary use.[11] Specifically, pharmacies must enter into provider agreements with State Medicaid Programs and with Medicare Part D Plan Sponsors agreeing to comply with all applicable laws and requirements when submitting claims for reimbursement. *See* 42 C.F.R. §

[11] *See ex rel. Wilkins*, 659 F.3d at 306 (recognizing express false certification liability under the FCA).

423.505(i)(4)(iv).[12] Numerous federal courts have held that false statements made in connection with Medicare or Medicaid enrollment and provider agreements can give rise to FCA liability.[13] Further, Janssen caused other health care entities (*e.g.,* the Medicare Part D Plan Sponsors) to falsely certify to the government that the claims were true, accurate, and complete. 42 C.F.R. § 423.505(k)(3). This additional evidence of falsity is a separate basis for Janssen's liability under the FCA.

F. Relators Will Establish Causation by Showing that Janssen's Conduct Was a Substantial Factor in Causing Physicians to Prescribe Prezista and Intelence Off-Label, and it was Foreseeable that False Claims Would Result

As this Court has recognized, causation is satisfied under the FCA if the defendant's conduct was a "substantial factor" in producing the false claims and it was "foreseeable" that false claims would result. (Dkt. 291, p. 19)*; see also United States ex rel. Schmidt v. Zimmer*, 386 F.3d 235, 244 (3d Cir. 2004).

Courts have consistently held that evidence of direct causation at a physician-by-physician or claim-by-claim level is not required to satisfy the substantial factor

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[13] *See*, *e.g.*, *United States ex rel. Greenfield v. Medco Health Systems, Inc.*, No. CIV. 12-522 NLH AMD, 2014 WL 4798637, at *10 (D.N.J. Sep. 26, 2014) (Medicare enrollment form); *United States ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683, 696–97 (N.D. Miss. 2012) (Medicare enrollment application); *United States ex rel. Osheroff v. Tenet HealthCare Corp.*, No. 09-22253-CIV, 2013 WL 1289260, at *3–5 (S.D. Fla. Mar. 27, 2013) (Medicare enrollment application and provider agreement).

test to prove causation in an FCA case.[14] In one of the first opinions discussing causation under the FCA at the summary judgment phase with respect to OL marketing, *United States ex rel. Franklin v. Parke-Davis,* No. CIV.A. 96-11651PBS, 2003 WL 22048255 (D. Mass. Aug. 22, 2003) ("*Franklin II*"), the court held that because the "FCA does not provide a special definition for causation," it would apply "common-law tort causation concepts." *Id.* at *4.[15] Hence, the relator must prove that "the defendant's conduct was a 'substantial factor' in producing the harm" and that the harm was foreseeable. *Id.* at *4–5.

Another FCA case addressing OL marketing also makes clear that proof of the defendant's systematic OL campaign will suffice to establish causation, and individualized proof on a doctor-by-doctor or patient-by-patient basis is not required in order for claims to go to a jury. In *United States ex rel. Brown v. Celgene Corporation,* 226 F. Supp. 3d 1032, 1040 (C.D. Cal. 2016), the court denied summary judgment to Celgene, rejecting its argument that the FCA claim failed

[14] *See United States ex rel. Colquitt v. Abbott Labs,* No. 3:06-CV-1769-M, 2016 WL 80000, at *7 (N.D. Tex. Jan. 7, 2016) (denying summary judgment on causation without requiring evidence that any provider ever relied on information or advice provided by defendants)*; Franklin II,* 2003 WL 22048255, at *5 (D. Mass. Aug. 22, 2003) (holding causation established in an OL marketing case without requiring proof that individual doctors relied on false statements by sales representatives).

[15] *See also Schmidt*, 386 F.3d at 244; *United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 416 (3d Cir. 1999) (applying tort law causation standard to find causation element established under the FCA).

because the plaintiff "fail[ed] to identify a particular false claim that was presented as a result of its OL promotion." The evidence in *Celgene* showed that the defendant had "engaged in a systematic campaign to promote OL prescriptions of its drugs, that physicians who received more promotional contacts prescribed at a higher rate than those who received fewer contacts, and that claims for OL prescriptions were presented to the government in the hundreds of thousands following Celgene's promotional activities." *Id.* The court deemed this evidence sufficient for causation and denied summary judgment. Relators will present all of this same evidence—and more—at trial here. This Court has embraced the *Celgene* opinion and found that "Relators are 'not required to identify a particular false claim caused by [Janssen's] off-label promotion.'" (Dkt. 291, p. 19).

Janssen has argued that a causal connection between its OL marketing campaign and doctors' decisions to prescribe Prezista and Intelence cannot be established because of the intervening decision-making of doctors when prescribing the drugs. But contrary to such a contention, such independent factors do not break the causal chain in this case. Under the law, the fact that Janssen marketed its drugs OL to prescribers who wrote the prescriptions does not defeat a showing of causation, particularly since the goal of Janssen's nationwide OL marketing

campaign was to influence doctor's prescribing behavior (that is, to increase total prescriptions written by prescribers).[16]

In *In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013), the court rejected defendants' argument that "because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors are independent intervening causes." *Id.* at 39. The court explained that "'[o]nce a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct,' the burden shifts to the defendant to rebut this causal inference." *Id.* at 45. Thus, even if Janssen presents testimony of doctors saying that their decisions to prescribe Prezista or Intelence were not influenced by Janssen's fraudulent marketing, the jury could reject those contentions and weigh the evidence as it deems appropriate.

Relators intend to prove that Janssen's widespread OL marketing campaign was a substantial factor in causing physicians to prescribe Prezista and Intelence OL, and it was reasonably foreseeable that this would result in the submission of OL claims for reimbursement to the government. Indeed, the evidence establishes that

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[16] *See United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 52–53 (D. Mass. 2001) ("*Franklin I*") (finding causation met and rejecting defendant's argument that "the actions of the[] [physicians] were an intervening force that br[oke] the chain of legal causation"); *see also Franklin II,* 2003 WL 22048255 at *4–5; *see also In re Avandia Marketing, Sales Practices and Prod. Liab. Litig.*, 804 F.3d 633, 645 (3d Cir. 2015).

Janssen intended this very result. Accordingly, under the established precedent of the Third Circuit, such proof establishes FCA causation.

G. Relators Will Prove that Janssen's Illegal Conduct Could Have Impacted the Government's Payment Decisions, and thus, was Material

Under the holistic approach for determining materiality in FCA cases, embraced by the Supreme Court in *Escobar*, Relators can satisfy the materiality element by proving that: (1) Janssen's conduct violated an express condition of payment; the violations go to the "essence of the bargain" for reimbursement by Medicare and Medicaid; (2) the government routinely devotes significant efforts to fighting and preventing fraud stemming from pharmaceutical manufacturers' off - label marketing; and (3) Janssen was aware that the government attaches importance to addressing such fraud. *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192–96 (2016). When denying Janssen's Motion for Summary Judgment, this Court embraced these factors, and found that "Relators have identified evidence in the form of expert testimony from which a jury could conclude that Janssen's conduct violated an express condition of payment, which would tend to show that it was material to the Government's decision to reimburse the claim." (Dkt. 291, p. 23) (*citing Escobar*, 579 U.S. at 193).[17]

[17] In *Escobar*, the Supreme Court reaffirmed that the proper test for determining materiality in FCA cases is whether the conduct at issue has "a natural tendency to influence, or [is] capable of influencing, the payment or receipt of money or

Also, to show materiality, Relators need not adduce evidence directly from a government official saying that if the government had known the various ways in which Janssen promoted Prezista and Intelence OL, then the government would *have made* different payment decisions. Such evidence is not required by law. *See* 31 U.S.C. § 3729(b)(4) (definition of "material"). Also, Relators need not show that the government *would have made* different payment decisions, as such requirement conflicts with the FCA's materiality standard (*i.e.,* "natural tendency to influence") and has been rejected by courts.[18]

1. The Government Explicitly Conditions Payment on Whether Prescriptions are for Medically Accepted Indications or are Reasonable and Necessary

The government's express conditioning of payment on compliance with the requirement that a drug be prescribed for an FDA-approved indication or be

property." 579 U.S. at 182 (*citing* 31 U.S.C. § 3729(b)(4)). The test is an objective one, but subjective understandings may be relevant to what a reasonable person would consider material. Thus, the materiality test is satisfied either if a "reasonable man would attach importance" to the misrepresentation or the "defendant knew or had reason to know that the recipient of the representation attached importance to it." *Id.* at 193.

[18] *See also* United States' SOI Regarding Defendant's Motion to Dismiss, *United States ex rel. Gardner v. Vanda Pharm., Inc.*, ECF # 58, Civ. No. 17-cv-00464, at p. 3 (D.D.C. December 1, 2020) ("*Escobar* therefore does not require a showing that the government 'would' have denied payment, which is tantamount to an outcome standard of materiality at odds with the text of the FCA."); *see also ManTech*, 600 F. App'x. at 967–77.

medically reasonable and necessary strongly supports a finding of materiality. *See Escobar*, 579 U.S. at 193; *see also United States ex rel. Doe v. Heart Solution, PC*, 923 F.3d 308, 318 (3d Cir. 2019) (holding the government "met its burden when it submitted that, pursuant to the regulation, Medicare would not pay the claims in the absence of a certification from a supervising neurologist."). Relators allege that OL-induced claims for prescriptions of Prezista and Intelence were false because they were not for medically accepted indications or they were not "reasonable and necessary."[19] As the court in *Celgene* concluded, a medically accepted indication is an explicit condition of payment under Medicare Part D, and "[w]hile that may not be 'automatically dispositive' of the materiality inquiry, we think it highly "relevant." *Celgene*, 226 F. Supp. 3d at 1049. Further, "[e]ven if the medical acceptance requirement is not per se material, we think a genuine dispute of material fact exists as to whether the requirement was material to the payment decisions at issue here." *Id.* Similarly, here, the government expressly requires that reimbursement is limited to prescriptions that are for medically accepted indications and that are reasonable and necessary.

[19] *See* 42 U.S.C. § 1395w-102(e)(1), (e)(3); 42 U.S.C. § 1395y(a)(l)(A); 42 U.S.C. § 1396r-8(d)(1)(B)(i); 42 C.F.R. § 411.15(k)(1); *see also* 42 C.F.R. § 423.505(i)(4)(iv) (pharmacies' contracts with the Part D plan sponsors must contain language obligating the pharmacies to "comply with all applicable Federal laws, regulations and CMS instructions" when submitting claims for reimbursement).

2. Government Reimbursement for Prescriptions that are Off-Label or Not Reasonable and Necessary Goes to the "Essence of the Bargain"

Escobar held that violations of the law or regulations that go to the "essence of the bargain" between a contractor and the government are likely to be material to the government's decision to pay. 579 U.S. at 193, n.5. In *Celgene*, the court explained that noncompliance with an express condition of payment may be so "central to the functioning of a government program that noncompliance is material as a matter of law." 226 F. Supp. 3d at 1049. Likewise, here any reasonable person would consider the medical necessity of a drug or whether it was being prescribed for medically accepted indications as critical considerations for payment of the claims for that treatment.[20]

Any assertion by Janssen that materiality is not established because the government got "what [it] had bargained" for, in that HIV drugs were prescribed for HIV patients, would be misplaced. Nothing in the federal policy of treatment for HIV patients overrides the medically accepted standards governing appropriate medical treatment, the FDA-approved indications of a drug, or payment for only such approved uses. The relevant focus for materiality is on Janssen's conduct and

[20] *See United States ex rel. Prather v. Brookdale Senior Living Comm., Inc*., 892 F.3d 822, 825, 834 (6th Cir. 2018) (physician certification that "attest[ed] to the need for the medical services," went to "the essence of the bargain between themselves and the government").

whether, based on the totality of the relevant factors, if the government were aware, it could be material to the government's payment decision.

3. The Government Devotes Significant Efforts to Combat Off-Label Marketing

The government has devoted significant resources to fighting false and OL marketing through multiple task forces, hearings, public pronouncements, hotlines, prosecutions, and settlements. These varied and wide-ranging efforts demonstrate the significance to the government of stopping OL marketing. For example, CMS has many resources specifically targeted to combat illegal OL promotion of drugs. Further, the government has made multiple avenues available for observers to report off-label marketing, indicating the importance that the government attaches to avoiding both the patient harm and the government expense of such conduct. There have also been numerous Congressional hearings addressing off-label marketing.

With regard to similar case settlements, significantly, the court in *Teva* found that the "[r]elators' *strongest evidence* [of materiality was] that the Government ha[d] enforced the FCA against pharmaceutical companies for similar behavior [AKS violations related to their speaker programs]." 2019 WL 1245656, at *30 (emphasis added); *see also United States ex rel. Rose v. Stephens Institute*, 909 F.3d 1012, 1020–21 (9th Cir. 2018) (denying summary judgment as the government's actions showed the importance of the violation at issue in the case because the government issued fines and entered into settlements totaling tens of millions of

dollars in similar cases). Here, there have been enormous settlements in FCA cases related to OL marketing, including settlements involving Janssen. In fact, the Court has already ruled that Janssen's Corporate Integrity Agreements and settlements with the government involving speaker programs and allegations of off-label promotion and kickbacks are relevant to the FCA elements of scienter and materiality in this action. (Dkt. 330, pp. 12-16).

III. JANSSEN IS LIABLE FOR THE CONDUCT OF ALL EMPLOYEES WHO ACTED WITHIN THE SCOPE OF THEIR EMPLOYMENT

At trial, Relators will present evidence that numerous Janssen employees, acting within the scope of their employment and under the direction of senior executives and the employees' direct supervisors, knowingly and willfully promoted Prezista and Intelence for OL purposes and provided kickbacks to doctors, thereby causing false claims to be submitted to government health care programs. These unlawful actions should all be imputed to defendant Janssen.

It is well-established that employers may be held liable under the FCA for the conduct of their employees within the scope of their employment. *See United States ex rel. Jones v. Brigham and Women's Hosp.*, 678 F.3d 72, 82 n.18 (1st Cir. 2012) ("We have long held that corporate defendants may be subject to FCA liability when

the alleged misrepresentations are made while the employee is acting within the scope of his or her employment.").[21]

Courts impute to corporate employers the knowledge of fraud by their employees because the employees gained such knowledge in the scope of employment. *See United States v. Anchor Mortg. Corp.*, 711 F.3d 745, 747–48 (7th Cir. 2013) ("Corporations . . . 'know' what their employees know, when the employees acquire knowledge within the scope of their employment and are in a position to do something about that knowledge."). Fraud committed by employees acting within the scope of their employment will be imputed to the corporate employer regardless of whether a manager or senior executive directed or was even aware of the employee's conduct. *See e.g.*, *Grand Union Co. v. United States*, 696 F.2d 888, 890–91 (11th Cir. 1983) (knowledge of food stamp fraud by low-level employees—"check-out cashiers" at a supermarket chain—"can be imputed to

[21] *See also United States ex rel. Cantekin v. University of Pittsburgh*, 192 F.3d 402 (3d Cir. 1999) (same); *see also United States v. Hangar One, Inc.*, 563 F.2d 1155, 1158 (5th Cir. 1977) (same); *see also United States v. Pierre Bouchet*, 1987 WL 11565 at *6 (S.D.N.Y. May 21, 1987) (granting summary judgment to the Government on FCA claim based on knowledge of fraud by corporate defendant's bookkeeper); *see also United States v. Inc. Village of Island Park*, 888 F. Supp. 419. 437–39 (E.D.N.Y. 1995) (granting summary judgment to the Government on FCA claim based on awareness of fraud by clerk).

[defendant]" under the FCA even though there was no evidence of "the head cashier's knowledge.").[22]

As courts have recognized, imputing to corporate defendants their employees' knowledge of fraud when such knowledge is gained in the scope of employment aligns with well-established principles of vicarious liability. Specifically, the court in *Village of Island Park* based its decision to impute knowledge of the village clerk to the municipal corporation employing him on long-standing tenets of tort and agency law. *See* 888 F. Supp. at 437 (adopting definitions of actual and apparent authority from Prosser on Torts and Restatement (Second) of Agency). Similarly, in *Williams Building*, the court concluded that holding the corporate defendant vicariously liable for the knowledge of its employee accords with basic principles of agency. 158 F. Supp. 2d at 1008 (relying on the Supreme Court's application of agency principles to impute knowledge of corporate employees to their employer in *A.S.M.E. v. Hydrolevel Corp.*, 456 U.S. 556, 566 (1982)).

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[22] *See also United States v. Associates in Eye Care, P.S.C.*, 2014 WL 414231, at *8 (E.D. Ky. Feb. 4, 2014) ("courts have found employers vicariously liable under the FCA for acts of employees when the employees acted within the scope of their employment" and "the government does not necessarily need to allege that [the corporate employer] endorsed or directed [the employee's] behavior for vicarious liability to attach"); *see also United States ex rel. Bryant v. Williams Building Corp.*, 158 F. Supp. 2d 1001, 1008 (D.S.D. 2001) ("[T]he majority of cases . . . hold a principal liable whenever its agent acts within the scope of employment or with apparent authority, regardless of the principal's knowledge, culpability, policies, or efforts to restrain the employee's bad acts.").

The "scope of employment" test for imputing knowledge of fraud to corporate defendants also accords with the core remedial and deterrent purposes of the FCA. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551 (1943) (stating the FCA's "chief purpose was to provide for restitution to the government of money taken from it by fraud"); *Rainwater v. United States*, 356 U.S. 590, 592 (1958) ("[T]he objective of Congress [in enacting the FCA] was broadly to protect the funds and property of the Government[.]"); *United States v. O'Connell*, 890 F.2d 563, 568 (1st Cir. 1989) (one of the FCA's purposes is "to deter fraud against the government"). More specifically, as the First Circuit recognized, "these goals are served by" applying tort principles of "vicarious liability" to FCA claims against corporations. *O'Connell*, 890 F.2d at 568. Further, legislative history makes plain that, when it amended the FCA to expand the definition of "knowingly" in 1986, Congress was well aware of the risks of fraud against the public fisc by corporate defendants and intended for the FCA to be "a more effective weapon against Government fraud." S. Rep. No. 99-345, at 4; *see also id*. at 7 (1986) (expansion of FCA's *scienter* definition intended to prevent "ostrich-like conduct" by "corporate officers [designed to] insulate themselves from knowledge of false claims"). Thus, the Court should adopt the "scope of employment" standard in this case.

IV. STATEMENTS BY JANSSEN PERSONNEL ARE ADMISSIBLE NON-HEARSAY

At trial, Relators and Relators' witnesses will testify that senior and mid-level personnel at Janssen directed them to engage in the unlawful actions at issue in this case regarding the OL marketing of the drugs and the improper use of remuneration to induce doctors' prescriptions. The statements by these employees fall within several exceptions to the hearsay rule, and they should therefore be admitted at trial.

First, statements made by Janssen employees are admissible non-hearsay statements that may be introduced against a party opponent under the Federal Rules of Evidence. Rule 801(d)(2)(D) provides that a statement is not hearsay if "the statement is offered against an opposing party and . . . was made by the party's agent or employee on a matter within the scope of that relationship and while it existed."[23] According to this Court:

> The offering party must make a threefold showing, through evidence independent of the proffered statement, that: (1) an employment relationship existed between the declarant and the party, (2) the statement was made during the agency or employment relationship, and

[23] This Court has recognized that under Third Circuit principles of agency law, an agency relationship is created when one party consents to have another act on its behalf. If the employer controls the time, manner, and method of executing the work, a master-servant relationship has been created. *See Condus v. Howard Sav. Bank*, 986 F. Supp. 914, 915–16 (D.N.J. 1997) (citing *American Tel. & Tel. Co. v. Winback and Conserve Program, Inc*., 42 F.3d 1421, 1434–35 (3d Cir. 1994)). Notably, Rule 801(d)(2)(D) refers to "agent or employee", and the declarants here may be considered both.

(3) the statement concerned a matter within the declarant's scope of employment.

See Glenn v. Scott Paper Company, No. CIV. A. 92-1873, 1993 WL 431161, at *11 (D.N.J. Oct. 20, 1993).

At trial, Relators will easily satisfy this three-part showing as the statements to be offered were made by employees of Janssen, during their employment, and they relate to matters squarely within the scope of their employment, namely, the promotion of Prezista and Intelence through sales calls and the Speaker Program. *See Ryder v. Westinghouse Elec. Corp*., 128 F.3d 128, 134 (3d Cir. 1997) (statements by a CEO made "to a group of . . . executives about personnel matters over which these executives exercised authority" were admissible as hearsay exceptions against a corporate party opponent).

Second, the statements made by these Janssen employees are admissible non-hearsay statements made by Janssen's co-conspirators during and in furtherance of a conspiracy under Federal Rule of Evidence 801(d)(2)(E). To admit such statements, the proffering party must show that: "(1) the conspiracy existed, (2) both the defendant and the declarant were members of the conspiracy, and (3) the statements were made in the course of the conspiracy and in furtherance of the conspiracy." *United States v. Bobb*, 471 F.3d 491, 498 (3d Cir. 2006). Also, this showing can be made at trial, and it does not need to be made before trial. *United States v. Escalante-Melgar*, No. CR16-453 (CCC), 2020 WL 968091, at *13–14

(D.N.J. Feb. 28, 2020); *see also United States v. Tejada*, No. CRIM.A. 12-312 JLL, 2013 WL 3786299, at *5 (D.N.J. July 17, 2013); *see also United States v. Blackwell*, 954 F. Supp. 944, 970 (D.N.J. 1997).

Significantly, the Third Circuit recognizes a distinction between conspiracy as a crime and the co-conspirator exception to the hearsay rule. As the Third Circuit explained, in contrast to the crime of conspiracy, "[t]he co-conspirator exception to hearsay rule . . . is merely a rule of evidence founded . . . on agency law." *United States v. Trowery*, 542 F.2d 623, 626 (3d Cir. 1976). "It may be applied in both civil and criminal cases." *Id.* Its "rationale" is "that a person who has authorized another to speak or to act toward some joint end will be held responsible for what is later said or done by his agent, whether in his presence or not." *Id.* "To determine whether the evidence is competent against the non-declarant," the court must determine "that a joint undertaking existed at the time of the statement or action." *Id.* at 627. "If the statement is admitted," then it may be admitted "as against all who are joint venturers." *Id.*

Thus, in the present case, to admit the declarants' statements against Janssen under this exception, Relators only need show that there was a joint venture between the declarants and Janssen, *i.e.*, that there was a "combination between them[.]" *Hitchman Coal & Coke Co. v. Mitchell*, 245 U.S. 229, 249 (1917). "[I]t is not necessary to show by independent evidence that the combination was criminal or

otherwise unlawful." *Id*. Relators will demonstrate that Janssen employees worked toward a common goal of increasing the sales of Prezista and Intelence through unlawful means. The employees' statements made in furtherance of that joint venture are admissible non hearsay as against Janssen.

Finally, these statements also fit within the hearsay exceptions as statements against interest under Federal Rule of Evidence 804(b)(3). To the extent that the declarants are not available to testify at trial, their statements are admissible if they are so far contrary to the declarants' pecuniary, proprietary, or penal interest that a "reasonable person in the declarant's position would not have made the statement unless believing it to be true." Fed. R. Evid. 804(b)(3); *Blackburn v. United Parcel Serv*., 179 F.3d 81, 96 (3d Cir. 1999); *Ebenhoech v. Koppers Industries, Inc*., 239 F. Supp. 2d 455, 464 (D.N.J. 2002). Again, given that this case involves allegations of massive health care fraud under the FCA and violations of the AKS, all systematically carried out under the direction of these senior and mid-level personnel, Relators will show at trial that Janssen employees' statements were objectively contrary to their own interests. *See United States v. Ashcroft*, 735 F.2d 101, 110 (3d Cir. 1984).

V. THE MEASURE OF DAMAGES IS A LEGAL QUESTION

Based on the opinions of Janssen's expert Dr. Jena, Janssen will likely argue that the government's damages should be broadly reduced based on a number of

factors. In particular, Janssen is likely to argue that (1) Relators' damages calculations must account for rebates Janssen might have paid to government payors; (2) Relators' damages calculations must deduct the "benefit of the bargain" allegedly received by government payors; and (3) Relators' damages calculations are limited to prescriptions written only for six months after prescribers were subjected to Janssen's influence. Janssen is incorrect on each of these arguments.

A. Janssen's Rebate and Government Benefit Arguments are Waived or Otherwise Not Questions for the Jury's Consideration

It is well-established that setoff, payment, mitigation, and similar damages avoidance arguments are affirmative defenses that must be pled and proven by a defendant. *Kutner Buick, Inc. v. Am. Motors Corp.*, 868 F.2d 614, 620 (3d Cir.1989) (reversing because the trial court incorrectly imposed the burden to "include in the [damages] calculation all offsets which would be proper mitigation of damages" on the plaintiff).[24]

To the extent Janssen seeks to challenge Relator's damages calculations for allegedly failing to reduce the amounts paid by government payors by any rebates

[24] *See also S.J. Groves & Sons Co. v. Warner Co.*, 576 F.2d 524, 529 (3d Cir. 1978) ("The burden of proving that losses could have been avoided by reasonable effort and expense must be borne by the party who has broken the contract."); *see also Herlihy Moving & Storage, Inc. v. Adecco USA, Inc.*, 772 F. Supp. 2d 898, 899 (S.D. Ohio 2011) ("'[T]he defendant who seeks to take advantage of [a] setoff credit bears the burden of proving the amount of credit to which he is entitled.'"); *Regency Commc'ns, Inc. v. Cleartel Commc'ns, Inc.*, 304 F. Supp. 2d 1, 6–7 (D.D.C. 2004) ("Setoff is an affirmative defense under Federal Rule of Civil Procedure 8(c).").

Janssen might have paid back to the government, that is a quintessential affirmative defense of payment or offset that Janssen must plead and prove. However, Janssen failed to plead any such affirmative defense in this action, and the parties did not conduct discovery on the amount or value of any such payments to the government from Janssen or any alleged offset. Further, Janssen did not put any affirmative defenses at issue in the Final Pretrial Order entered November 2, 2022. Relators do not have the burden of proving any offsets or payments made by Janssen, and Janssen has waived this affirmative defense. *Charpentier v. Godsil*, 937 F.2d 859, 863 (3d Cir. 1991) ("Failure to raise an affirmative defense by responsive pleading or by appropriate motion generally results in the waiver of that defense."); *see also Beemac, Inc. v. Republic Steel*, No. 2:20-CV-1458, 2023 WL 414395, at *4 (W.D. Pa. Jan. 25, 2023) ("Republic also could have asserted an affirmative defense based on its offset theory, but chose not to; thus, waiving its right to assert such a defense.").

Likewise, had it not waived the affirmative defense, Janssen would bear the burden of proving the value of any goods or services received by the government that would offset the amounts paid as a result of false claims caused by Janssen. Janssen's expert Dr. Jena couches that argument in terms of "benefit of the bargain" damages. However, that argument is misplaced because the case law applicable to FCA damages arising from health care fraud roundly rejects any such measure of

damages. Indeed, in health care subsidy programs like Medicare and Medicaid, the government receives no tangible benefit—only a bill to pay for goods or services that purport to comply with conditions of payment.[25] As stated by the Seventh Circuit Court of Appeals:

> "Edgewater did not furnish any medical service to the United States. The government offers a subsidy (from the patients' perspective, a form of insurance), with conditions. **When the conditions are not satisfied, nothing is due. Thus, the entire amount that Edgewater received on these 1,812 claims must be paid back.** Now it may be that, if the patients had gone elsewhere, the United States would have paid for their care. Or perhaps the patients, or a private insurer, would have paid for care at Edgewater had it refrained from billing the United States. But neither possibility allows [defendant] to keep money obtained from the Treasury by false pretense, or avoid the penalty for deceit."

United States v. Rogan, 517 F.3d 449, 453 (7th Cir. 2008) (emphasis added).

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[25] *See United States ex rel. Lutz v. BlueWave Healthcare Consultants, Inc.*, No. 9:11-CV-1593-RMG, 2018 WL 11282049, at *1–3 (D.S.C. May 23, 2018) (in case involving both AKS and medical unnecessary claims, court upheld jury's damages verdict, where jury found damages for full value of the false claims); *see also United States v. Robinson*, No. CV 13-27-GFVT, 2016 WL 7030447, at *5–7 (E.D. Ky. July 8, 2016) (denying motion for new trial where jury awarded government full value of all of defendant's optometry claims it determined were medically unnecessary); *see also United States v. Healing Corner LLC*, No .19-CV-1791-JPS, 2023 WL 2270492, at *5–6 (E.D. Wis. Feb. 28, 2023) (in default judgment proceeding, granting government's requested damages figure, which consisted of the entire cost of medically unnecessary substance abuse treatment services); *see also United States ex rel. Landsberg v. Argentis Medical, P.C.*, No. CV 03-1263, 2009 WL 10727191, at *5–6 (W.D. Pa. March 12, 2009) (in default judgment proceeding, granting single damages equal to full amount of federal compensation for medically unnecessary ultrasound testing); *see also United States v. Acadiana Cardiology, LLC*, No. CIV.A. 04-732, 2014 WL 1320157, at *5 (W.D. La. Mar. 27, 2014) (damages for medically unnecessary cardiac procedures was full value of the claim).

Indeed, it is well-settled that when the government receives no tangible benefit from the defendant (as is the case here), or when the defendant's FCA violation qualitatively impacts the very purpose of the government program or requirement (again, as is the case here), the government is entitled to recover the full amount it paid out without any offset.[26] In other words, the proper measure of damages is the full amount that the government paid as a result of false claims caused by Janssen because all claims were ineligible for reimbursement. *See United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386–87 (4th Cir. 2015) (finding that

[26] *See also United States ex rel. Feldman v. Van Gorp.*, 697 F.3d 78 (2d Cir. 2012); *see also United States ex rel. Longhi v. Lithium Power Tech.*, 575 F. 3d 458, 472–473 (5th Cir. 2009); *see also United States v. Rogan*, 517 F. 3d 449, 453 (7th Cir 2008); *see also United States v. Mackby*, 339 F.3d 1013, 1018–19 (9th Cir. 2003); *see also United States ex rel. Layman v. Bombardier Transp. (Holdings) USA, Inc.*, 656 F. Supp. 2d 540, 546 (W.D. Pa. 2009). Courts have adhered to this rule when the defendant submits bills to the government in violation of the AKS. *See Rogan*, 517 F. 3d at 452; *United States v. Teva Pharms USA Inc.,* No. 20-cv-11548 NMG, Dkt 64, pp. 6–7 (D. Mass. June 7, 2022) ("As a matter of law, however, damages for violations of the FCA predicated on violations of the AKS are measured as the entirety of the government's payments for claims tainted by those illegal kickbacks"); *see also United States ex rel. Emanuele v. Medicor Assocs.*, No. CV 10-245, 2017 WL 4867614, at *9 (holding that "courts have typically awarded a full measure of damages" since the United States is explicitly barred by law from making any payment tainted by a kickback) (collecting cases); *United States ex rel. Freedman v. Suarez-Hojos*, No. 8:04-CV-933-T-24 EAJ, 2012 WL 4344199, at *4 (M.D. Fla. Sept. 21, 2012) ("[T]he amount of the Government's damages resulting from the payment of false claims tainted by a kickback arrangement equals the full amount that Medicare paid on such claims").

FCA damages are the full amount paid by Medicare for reimbursements for claims submitted in violation of the Stark Law).[27]

And even if (1) Janssen had not waived its affirmative defenses of payment and offset and (2) offsets were available for health care fraud damages, any such value to the government that Janssen could prove would only be deducted from FCA damages *after trebling*. The United States Supreme Court established that order of operations decades ago:

> [I]n computing the double [now treble] damages authorized by the [False Claims] Act, the Government's actual damages are to be doubled [now trebled] before any subtractions are made for compensatory payments previously received by the Government from any source.

United States v. Bornstein, 423 U.S. 303, 316 (1976); *see also United States v. Globe Remodeling Co.*, 196 F. Supp. 652, 657–658 (D. Vt. 1960) (finding that offset for "repayments to the government from the borrowers who defaulted" should be made "after doubling the original losses"); *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 501 F. Supp. 2d 51, 54 (D.D.C. 2007) ("With respect to damages under

[27] *United States ex rel. Longhi v. Lithium Power Tech., Inc.*, 575 F.3d 458, 473 (5th Cir. 2009) (affirming summary judgment that FCA damages were full amount paid out by Government); *United States v. Teva Pharmaceuticals USA, Inc.,* 2023 WL 4565105, at *5–6 (D. Mass. July 14, 2023) (since the government would not have paid claims submitted in violation of the AKS, "the Court will measure damages in this case as the entirety of the government's payments for the claims resulting from the illegal kickbacks"); *ex rel. Emanuele*, 2017 WL 4867614, at *10 (W.D. Pa. Oct. 26, 2017) (ruling that the proper measure of damages was the full amount of the government payments for services that it was legally prohibited from paying due to illegal referrals or kickbacks).

the FCA, the U.S. Supreme Court has found that the actual *damages must first be multiplied* pursuant to the statute, *and then be reduced by any compensatory payments* previously received by the Government[.]") (emphases added).

B. <u>There is no Six-Month or other Temporal Cut Off for Damages</u>

Under the law, damages must include all reimbursements that government payors paid as a result of OL claims and kickback-tainted claims caused by Janssen. Janssen will likely assert the position, based on the opinions of Dr Jena, that any prescriptions written by doctors six months after they were subjected to Janssen's improper influence (OL marketing or kickbacks) should be excluded from damages. This is incorrect as a matter of law.

Neither the FCA, the AKS, nor the relevant case law supports a six-month cut off, or any temporal cut off, for damages. In *United States ex rel. Fesenmaier v. Cameron-Ehlen Group, Inc.,* the Court rejected the defendants' argument that the plaintiffs' use of a one-year taint period following the payment of a kickback should be shortened for purposes of demonstrating proximate cause. The Court stated:

> **Nothing in the FCA or the AKS imposes a strict temporal cutoff such that a false claim ceases to be false if a certain amount of time has passed between the fraudulent conduct and the submission of the claim.**…Moreover, Plaintiffs have presented evidence that substantiates their use of a one-year taint period, including evidence that physicians tend to stick with a lens choice for a long period of time. As such, Defendants have not established that Plaintiffs' one-year 'taint' period renders Plaintiffs' causation evidence insufficient as a matter of law.

2021 WL 101193, at *13 (emphasis added). Similarly, in *Teva*, 2019 WL 1245656 at *23–24, the Court rejected the defendant's argument to cut off damages at some future time period, and found that if a defendant engaged in a company-wide kickback scheme through its speaker program, then all of the speaker's prescriptions can be included in damages. In fact, there is no legal basis—in the FCA, AKS, or in case law—supporting a six-month, one-year, or any other "taint" period that serves as a basis to cut off damages stemming from Janssen's submission of false or fraudulent claims.

VI. CORPORATE REPRESENTATIVE TESTIMONY

In the Final Pretrial Order, Relators indicated they might seek the Court's permission to call a Janssen corporate representative to testify at trial (Dkt. 315, p. 2). The Court directed Relators to brief the issue in their trial brief or at trial. At this time, Relators do not intend to seek testimony from a Janssen corporate representative on substantive issues. In the event, during trial, Relators determine that the need arises to seek corporate representative testimony, Relators will submit a brief as directed in the Final Pretrial Order.

VII. CONCLUSION

Relators look forward to trial in this matter and are prepared to brief any additional issues the Court would find helpful.

Date: April 5, 2024

Respectfully submitted,

By: /s/ William H. Ellerbe

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